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EXAMINER

ANGELL, JON E

ART UNIT PAPER NUMBER

1635

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/786,043

Applicant(s)

KOLA ET AL.

Examiner

J. Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 101-108 and 110-113 is/are pending in the application.
- 4a) Of the above claim(s) 101-108 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 110-113 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Action is in response to the communication filed on 3/4/03, as Paper No. 11. Claims 109 and 114-158 have been cancelled. Claims 110-113 have been amended. Claims 101-108 and 110-113 are pending in the application and are addressed herein.
2. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Election/Restrictions

3. It is respectfully pointed out that claims 101-108 have never been cancelled, and are presently pending. Therefore, claims 101-108 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention for the reasons of record, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9 (7/30/02).
4. This application contains claim 101-108 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

5. The disclosure is objected to because of the following informalities: It appears that the specification is replete with typographical errors. Specifically, it appears that throughout the specification contains either "<210>" or "<400>" where the phrase "SEQ ID NO:" should be (e.g. see pages 3-7, 16-18, 49, etc). It is respectfully pointed out that the sequence rules indicate that all nucleic acid sequences of 10 nucleotides or more and all amino acid sequences having more than 3 amino acids require designation with the appropriate sequence identifier (i.e. SEQ ID NO). A proper CRF and paper sequence listing has been received and appears to correspond with the <210> and <400> listings mentioned. Therefore, correcting the specification by substituting "SEQ ID NO:" for "<210>" and "<400>" as appropriate would obviate this objection.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 111-113 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 111 is drawn to an isolated nucleic acid molecule comprising a nucleotide sequence substantially as set forth in SEQ ID NO: 1 capable of hybridizing to SEQ ID NO: 1 under medium stringency conditions.

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The phrase “substantially as set forth in SEQ ID NO: 1” renders this claim indefinite because the exact sequence encompassed by the claim is not clear. For instance, one of skill in the art would not readily recognize a nucleic acid that is substantially as set forth in SEQ ID NO: 1 that is capable of hybridizing to SEQ ID NO: 1 under medium stringency conditions.

Amending claim 111 to recite, “An isolated nucleic acid molecule comprising the nucleotide sequence set forth in SEQ ID NO: 1, wherein said nucleic acid molecule hybridizes to SEQ ID NO: 1 under medium stringency conditions” would obviate this rejection.

Claim 112 depends on claim 11 and is rejected for the same reason.

Claim 113 recites the phrase, “An isolated nucleic acid molecule according to claim 110, as set forth in SEQ ID NO: 1.” This phrase renders the claim indefinite because it is unclear if the nucleic acid sequence is the exact and complete nucleic acid sequence of SEQ ID NO: 1, or if the nucleic acid sequence merely comprises a nucleotide sequence encoding an amino acid sequence having at least 45% similarity to SEQ ID NO: 2. Amending claim 113 to recite, “An isolated nucleic acid sequence comprising the sequence set forth in SEQ ID NO: 1.” would obviate this rejection.

Claim Rejections - 35 USC § 112, first paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 110-113 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 110 and 112 encompass an isolated nucleic acid molecule comprising a nucleotide sequence encoding, or a nucleic acid sequence complementary to a nucleotide sequence encoding, an amino acid sequence as set forth in SEQ ID NO: 2, or having at least 45% similarity to SEQ ID NO: 2. This claim encompasses any nucleic acid sequence that encodes an amino acid sequence that is 45% similar to SEQ ID NO: 2. Therefore, this claim encompasses any variant or fragment of SEQ ID NO: 1 that encodes an amino acid sequence 45% identical to SEQ ID NO: 2.

Claim 111 is drawn to an isolated nucleic acid molecule comprising a nucleotide sequence substantially as set forth in SEQ ID NO: 1 capable of hybridizing to SEQ ID NO: 1 under medium stringency conditions. Therefore, the claim encompasses any derivative/fragment of SEQ ID NO: 1 that could hybridize to SEQ ID NO: 1 under medium stringency.

As mentioned above, claim 113 can be interpreted as a nucleic acid sequence comprising a nucleotide sequence encoding an amino acid sequence having at least 45% similarity to SEQ ID NO: 2. Therefore claim 113 encompasses any nucleic acid sequence of SEQ ID NO: 1 that encodes an amino acid sequence that is at least 45% similar to SEQ ID NO: 2, including variants and fragments of SEQ ID NO: 1 which are not adequately described in the specification and also including unidentified naturally occurring allelic variants.

Therefore, the instant claims encompass sequences which are different from those disclosed in the specification, and include variants, derivatives and analogues for which there is

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insufficient written description provided in the specification. The specification discloses only the full-length sequence of SEQ ID NO: 1 which encodes the full-length sequence of SEQ ID NO: 2. Thus, applicant has express possession of only the full length sequences of SEQ ID NOS: 1 and 2 in a genus which comprises hundreds of millions of different species possibilities considering every possible variant/derivative/analogue that is 45% identical to (or encodes a sequence 45% identical to) SEQ ID NO: 2.

The Written Description Guidelines for examination of patent applications indicates, “the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus.” (See MPEP 2100-164)

As mentioned above, and in the previous Office Action, the claims encompass sequences for which there is and insufficient description provide in the specification. Specifically, the claims encompass nucleic acid molecules which encode an amino acid sequence which is 45% similar to SEQ ID NO: 2 and an isolated nucleic acid molecule comprising a nucleotide sequence substantially as set forth in SEQ ID NO: 1 capable of hybridizing to SEQ ID NO: 1 under medium stringency conditions.

The specification does not adequately describe the functional sequences that are 45% similar to the amino acid sequence of SEQ ID NO: 2 (or a nucleic acid encoding the sequence that is 45% similar to SEQ 2). The specification only describes one species of the claimed genus

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of amino acid sequences—the sequence set forth in SEQ ID NO: 2; and only one species of nucleic acid sequence encoding the amino acid sequence—the sequence set forth in SEQ ID NO: 1 which encodes the sequence of SEQ ID NO: 2. The specification does not indicate the regions or domains of SEQ ID NO: 2 that are essential and those that are non-essential.

Without a clear indication of the critical and non-critical elements of SEQ ID NO: 2, one of ordinary skill in the art would not know which sequences 45% similar to SEQ ID NO: 2 would be functional sequences, without additional experimentation. Furthermore, one of skill in the art would readily recognize which sequences of SEQ ID NO: 1 are substantially similar enough to SEQ ID NO: 1 to be able to hybridize to SEQ ID NO: 1 under medium stringency conditions. Therefore, one of ordinary skill in the art would have to perform additional experimentation in order to identify the sequences which are substantially similar to SEQ ID NO:1 and encompassed by the claims.

Response to Arguments

35 USC 112, second paragraph:

Applicants have amended claims 110, 112 and 113, thus overcoming the rejection under 35 USC 112, second paragraph.

However, claim 111 still encompasses a nucleic acid “substantially as set forth in SEQ ID NO: 1 capable of hybridizing...” Applicants argue that metes and bounds of the subject matter of this claim are clear to those of skill in the art (see p. 4, first paragraph of the response). For the reasons stated above, this argument is not persuasive and the rejection is not withdrawn.

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Furthermore, the amendments to the claims have necessitated new rejections under 35 USC 112, second paragraph as set forth above.

35 USC 112, first paragraph:

Claim 109 has been cancelled, rendering the rejection of claim 109 moot. Applicant's arguments filed 3/4/03 regarding the rejections of claim 110-113 have been fully considered but they are not persuasive. Applicants argue that claim 110-113 have removed the language directed to homologues, derivatives and mimetics, thus overcoming the rejections (see p. 4 of the response).

In response, it is acknowledged that the have terms homologues, derivatives and mimetics have been removed from the claims; however, the claims still encompass derivatives and fragments for which there is insufficient written description, as mentioned above. Therefore, the amendments have not overcome the rejection of claims and the rejection is not withdrawn.

35 USC 102:

Claim 109 has been cancelled thus rendering the rejection of claim 109 moot. The rejection of claims 110-113 under 35 USC 102 have been withdrawn in view of the amendment and arguments. Specifically, the prior art does not teach an isolated nucleic acid molecule encoding an amino acid sequence that is 45% identical to SEQ ID NO:2, or an isolated nucleic acid sequence which would hybridize to SEQ ID NO: 1 under medium stringent conditions. Therefore, the rejection of claims under 35 USC 102 have been withdrawn.

Conclusion

No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for

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the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
May 16, 2003



DAVE T. NGUYEN
PRIMARY EXAMINER